

# **Exhibit 3**

## Laboratory analysis of varenicline products

FDA continues to investigate the presence of the N-nitroso-varenicline impurity in varenicline. Varenicline is a prescription drug used for smoking cessation. FDA has identified levels of N-nitroso-varenicline above FDA's acceptable intake limit in some samples of varenicline finished drugs.

FDA is posting its laboratory results in the table below showing N-nitroso-varenicline levels in varenicline products currently available for the U.S. market. Testing of varenicline is still ongoing, and FDA [posted \(/media/151470/download?attachment\)](/media/151470/download?attachment) its analytical method used in laboratory testing.

For reference, consuming up to the acceptable intake limit, 37 nanograms, of N-nitroso-varenicline per day is considered reasonably safe for humans, based on lifetime exposure. N-nitroso-varenicline may increase the risk of cancer if people are exposed to it above the acceptable intake limit and over a long period of time, but a person taking a drug that contains N-nitroso-varenicline at-or-below the acceptable intake limit every day for 70 years is not expected to have an increased risk of cancer. Agency scientists evaluated the risk of exposure to N-nitroso-varenicline at interim acceptable intake levels up to 185 ng per day (92.5 ppm) and determined that it presents minimal additional cancer risk when compared to a lifetime of exposure to N-nitroso-varenicline at the 37 ng per day (18.5 ppm) level.

Company (Manufacturer)	Product	Lots Tested	N-nitroso-varenicline level in micrograms/tablet (nanograms/tablet)	N-nitroso- varenicline level in parts per million (ppm)
Pfizer	Chantix (varenicline) 1mg	EA6080, EC9841, EC9847, EC9848, EX2099, DR5086	0.15-0.47 (150-470)	155-474
Par Pharmaceuticals	Varenicline 1 mg	31960807, 31960801	0.003 (3)	3
Apotex	APO-Varenicline Tartrate 1 mg)	TG2183, TG2181, TG2182	0.027-0.044 (27-44)	27-44
Apotex	APO-Varenicline Tartrate 0.5 mg	TG2180, TG2178, TG2179	0.014-0.021 (14-21)	27-42

As discussed in the July 16, 2021 CDER Statement update (/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-nitrosamine-varenicline-chantix), Apotex is distributing Apo-Varenicline, a Canadian-approved drug product, under FDA's temporary exercise of regulatory flexibility and discretion. Par Pharmaceutical's varenicline product was approved ([https://www.accessdata.fda.gov/scripts/cder/ob/results\\_product.cfm?Appl\\_Type=A&Appl\\_No=201785#39649](https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=201785#39649)) by FDA on August 11, 2021.